

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0391
CUSTOMER NUMBER: 1737

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Medimmune Vaccines, Inc.
297 North Bernardo Ave
Mountain View, CA 94043

(a)

forde-folk

b6 b7c

"H" by K. Danford 3/03/2006

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquilizi drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		14			14
7. Hamsters			254		254
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
FERRETS	31	1454		102	1556
COTTON RATS			25		25
					44

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and appropriate Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

b6 b7c DATE SIGNED

JAN 06

Column E Explanation

COPY FOR YOUR INFORMATION

1. Registration Number: 93-R-0391
2. Number of animals used in these studies: 102
3. Species (common name) of animals used in the study: Ferrets
4. Explain the procedure producing pain and/or distress.

The 102 ferrets assigned to Block E were used [REDACTED] research [REDACTED] and [REDACTED]. Infected ferrets studies may demonstrate [REDACTED] which may be but not [REDACTED]. The procedures involved did not cause the category E classification; rather it was the systemic [REDACTED] from the administration of the test articles that caused discomfort to the ferrets in this category. Due to the study design there is not allowance for alleviation of these signs with analgesics or [REDACTED] drugs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

In [REDACTED] research studies, there is concern that the use of analgesic agents will affect the [REDACTED] including the [REDACTED] and would therefore affect the results and interpretation of the studies performed.

The [REDACTED] is used as a positive control against which are measured [REDACTED] and performance of the [REDACTED]. The use of analgesics in these animals would invalidate this safety assessment.

In establishing [REDACTED] ferret model to monitor the ease of transmission from an otherwise healthy animal, the ferrets are treated [REDACTED] and the only way to reverse the side effect is to stop treatment. Stopping treatment would negate the results that we are trying to achieve.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: Food and Drug Administration (FDA) 21 CFR 610.1

Release Requirements: Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.



MedImmune Vaccines, Inc.

RECEIVED
U.S. POSTAL SERVICE

December 21, 2005

Mike Long
Inspection and Licensing Assistant
USDA, APHIS, Animal Care
Regional Office
Fort Collins, CO 80526

Dear Mr. Long:

I am responding to your request for a letter explaining why we are filing an amended Annual Report for 2005. During a recent inspection by Dr. Kim Folle, (Inspector ID: 5033) on December 5, 2005, she cited that the Annual Report should include retrospective information on animal use. Please see the attached form included with our amended report.

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MedImmune Vaccines, Inc.

JAN - 6 2006



MedImmune, Inc.

February 24, 2006

Kathleen M. Garland, VMO
Supervisory Animal Care Specialist
Western Region, Animal Care
USDA, APHIS
2150 Centre Avenue
Building B. 3W11
Ft. Collins, CO 80526

Customer Number: 1737
Registration No.: 93-R-0391

Dear Dr. Garland:

This letter is a reply to your correspondence dated February 10, 2006 which requested additional information for MedImmune Vaccine's Annual Report Amendment covering October 1, 2004 to September 30, 2005.

In the [REDACTED] Ferret model, [REDACTED] is used to [REDACTED]
[REDACTED] as a means to [REDACTED]. There is concern that the use of analgesic or [REDACTED] drugs to relieve possible discomfort would induce toxicity or affect [REDACTED] function of [REDACTED]. Toxicity due to a single or chronic dose may be broad ranging and may involve [REDACTED]
[REDACTED] as well as [REDACTED]. The development of any of these conditions would affect the development of the model and affect the interpretation of results of our assessment of susceptibility and [REDACTED] in this model [REDACTED]. There is also concern that the use of drugs such as analgesics, [REDACTED] to relieve pain or distress may induce hepatotoxicity. The implications are that hepatotoxicity may affect the metabolism, bioavailability and toxicity of [REDACTED]

Literature search using keywords [REDACTED]

[REDACTED]

Databases evaluated: AGRICOLA, Entrez-PubMed

Dates of search: unlimited to 18Feb2006

[REDACTED]

b4



The test governed by the 21CFR610.1 guideline requires that we use **b4** as a positive control against which the **b4** phenotype and performance of the **b4** is measured. The use of analgesics or **b4** drugs to relieve possible discomfort would invalidate this assessment.

Should you have any questions regarding this matter, please don't hesitate to contact **b6,b7c**

Sincerely,

b6,b7c

